UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFFS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT

ZHP and Its United States Subsidiaries Huahai US, Prinston, and Solco

[redacted]

[1] All exhibits in this Statement are attached to the Certification of Adam M. Slater in Support of Plaintiffs' Motion for Partial Summary Judgment.

[redacted]

[2] According to ZHP, Jun Du apparently retired sometime after sitting for his deposition in this case.

[redacted]

The Manufacture and Sale of Valsartan

[redacted]

[redacted]

[redacted]

[redacted]

The TEA With Sodium Nitrite Quenching Manufacturing Process

[redacted]

[redacted]

[redacted]

The Zinc Chloride Process

[redacted]

[redacted]

[redacted]

The NDMA/NDEA Contamination Levels in ZHP's Valsartan

[redacted]

[redacted]

[redacted]

[redacted]

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CEMAT And The July 27, 2017 Jinsheng Lin, Ph.D Email

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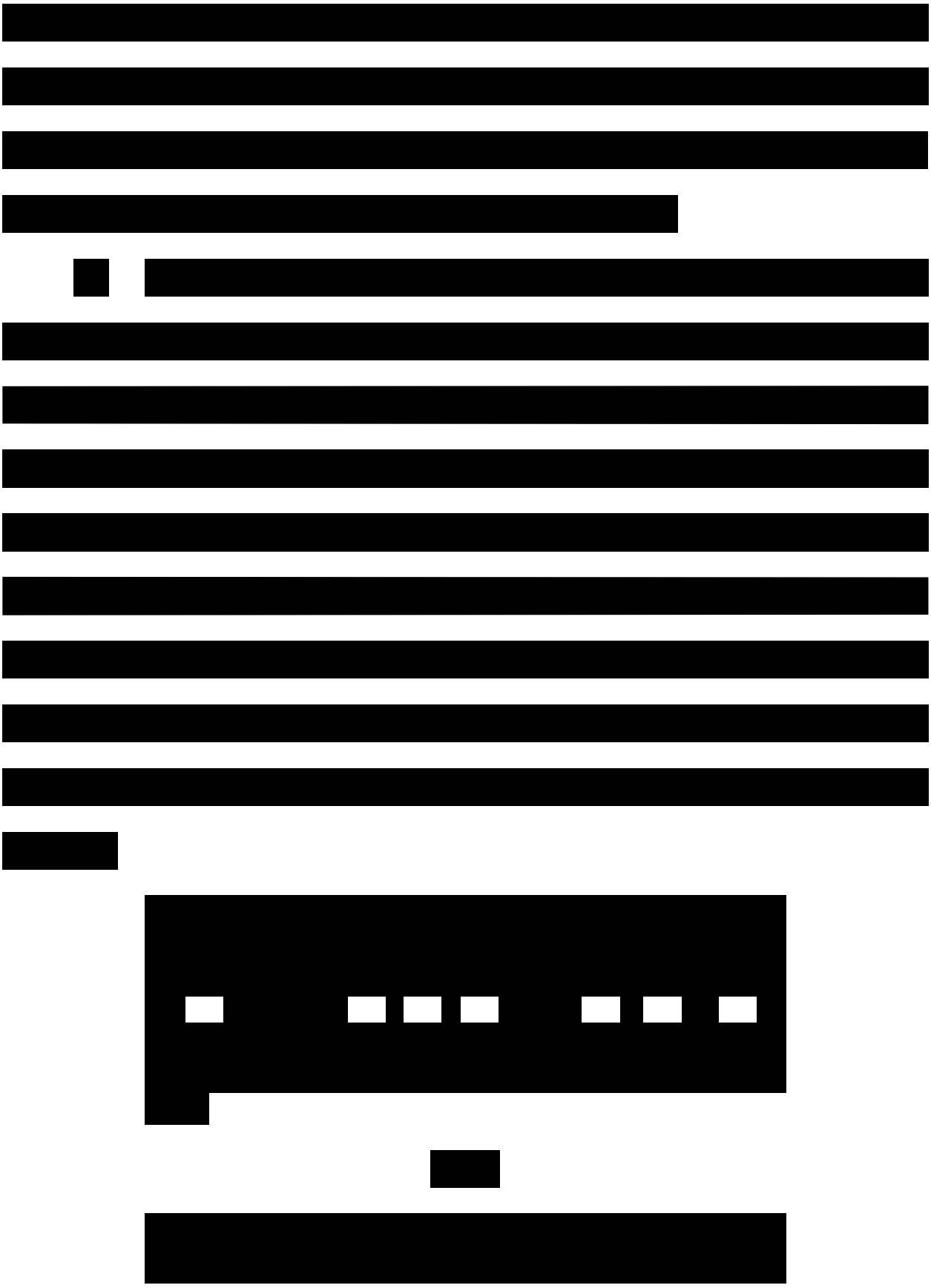

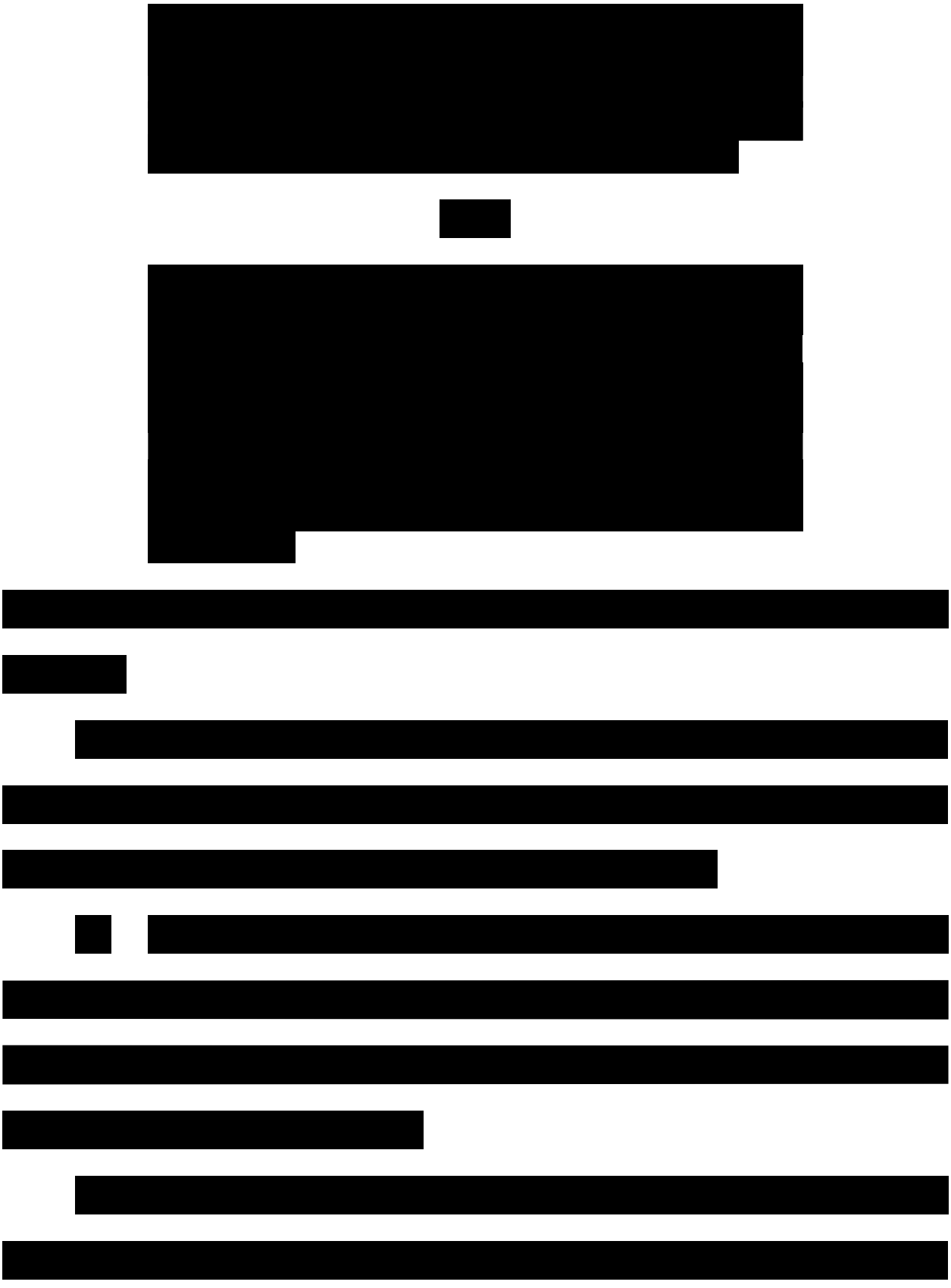

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CGMP Violations and Adulteration of ZHP's Valsartan:
The FDA Investigation and Findings

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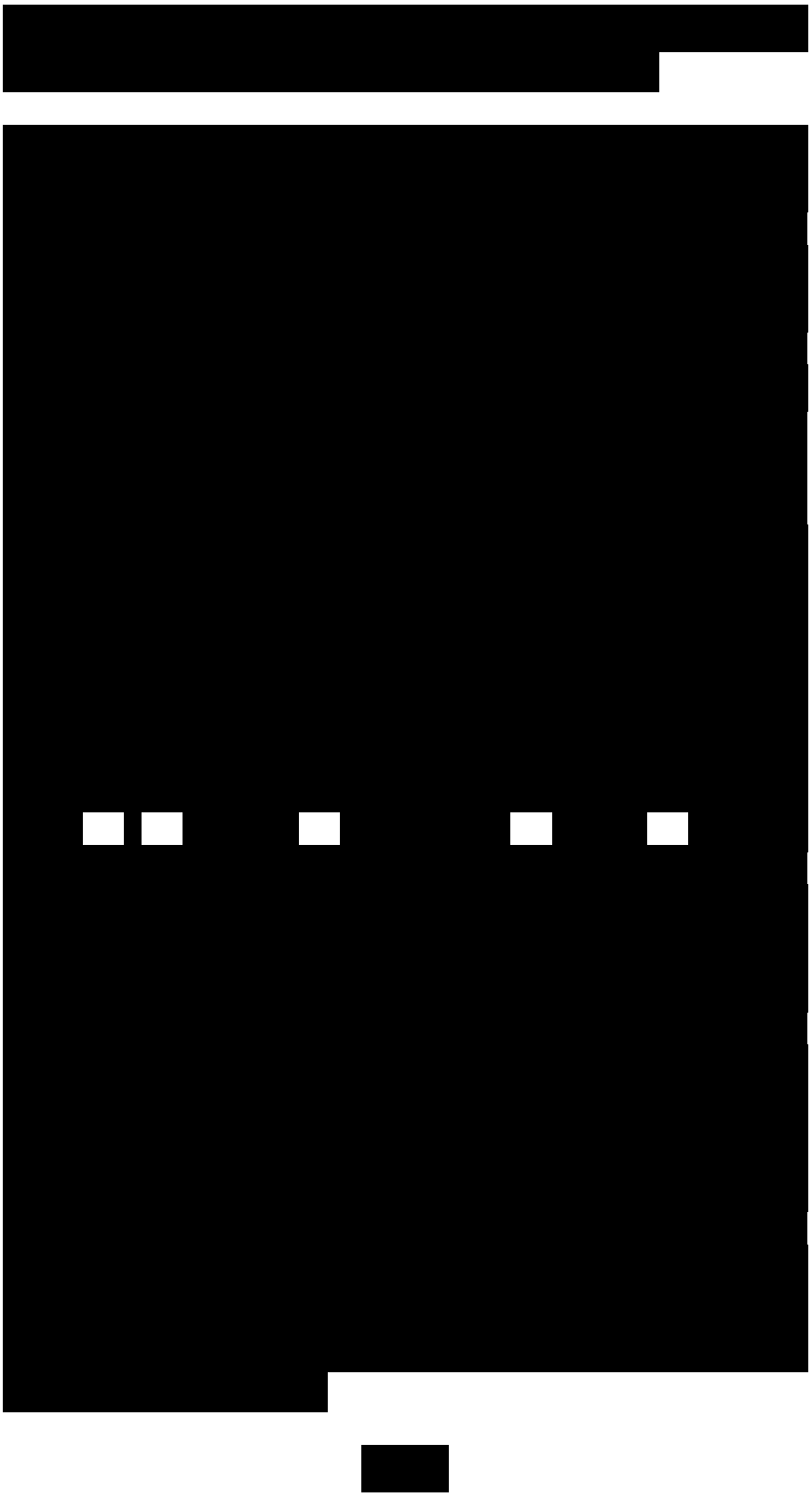

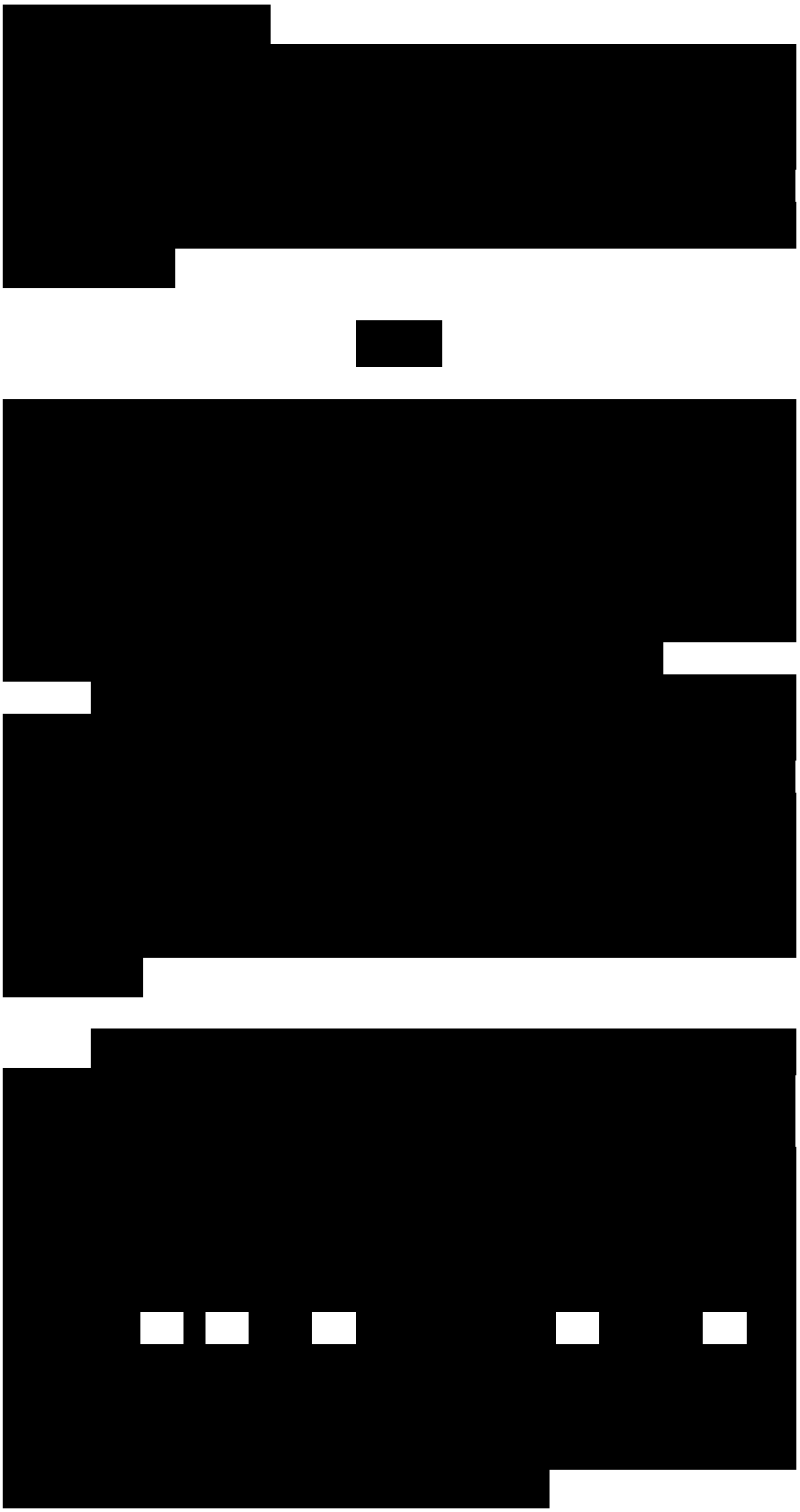

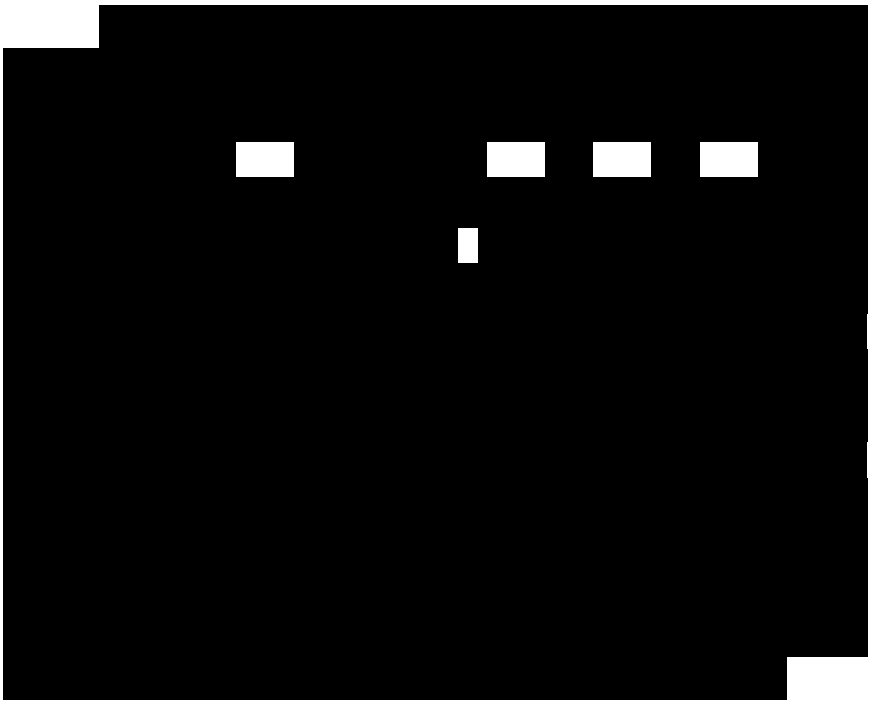

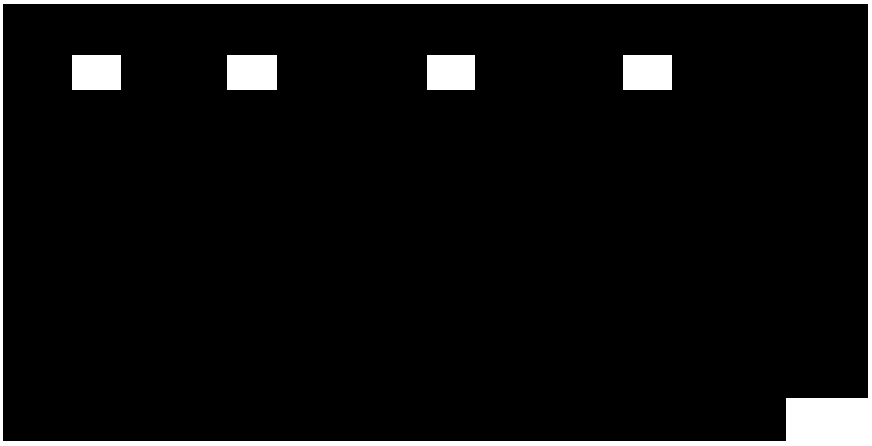

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(*Id.* at 1-3, 5-7) (emphasis added).

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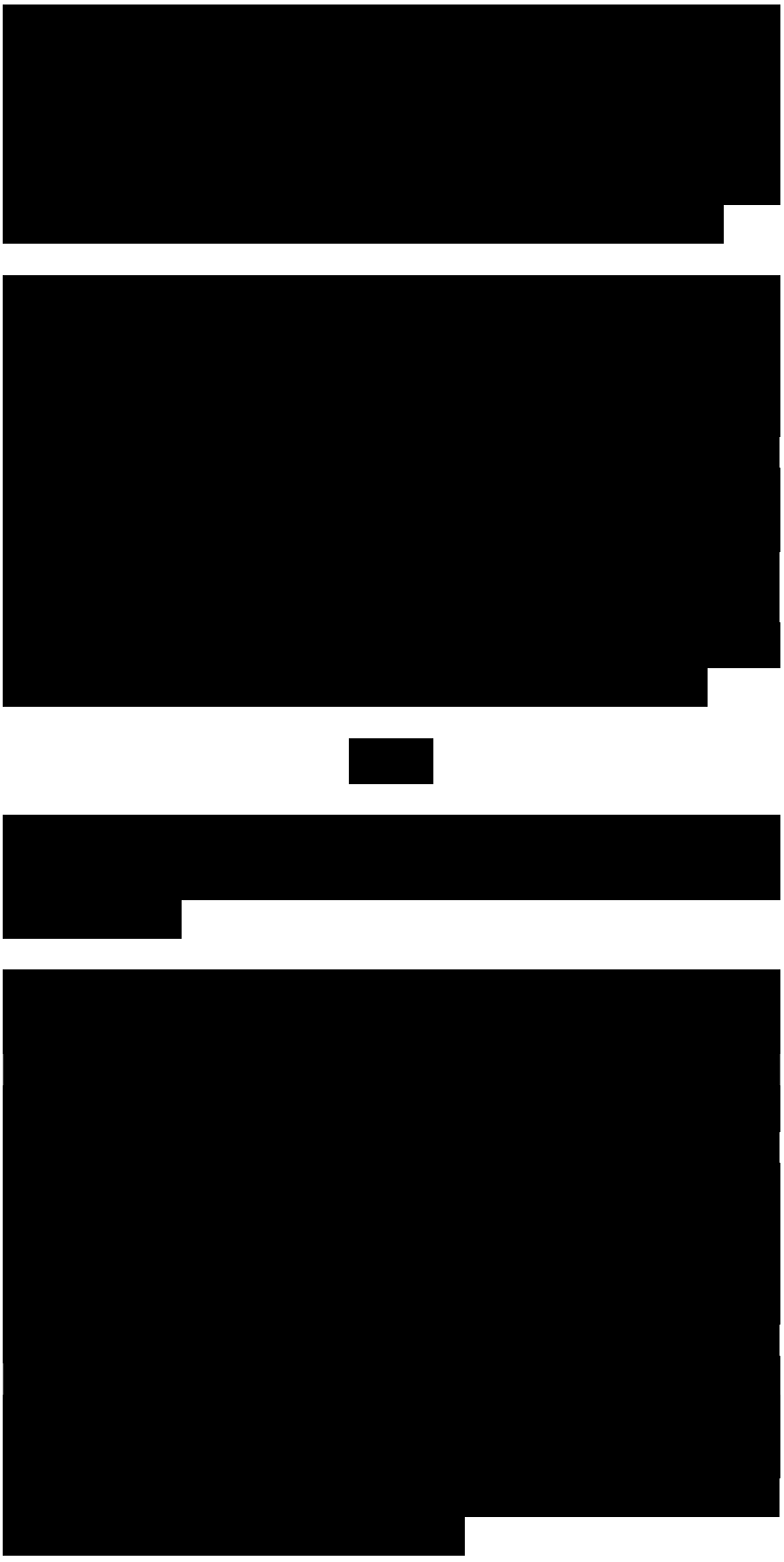

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ZHP'S Admissions Regarding Violations of cGMPs

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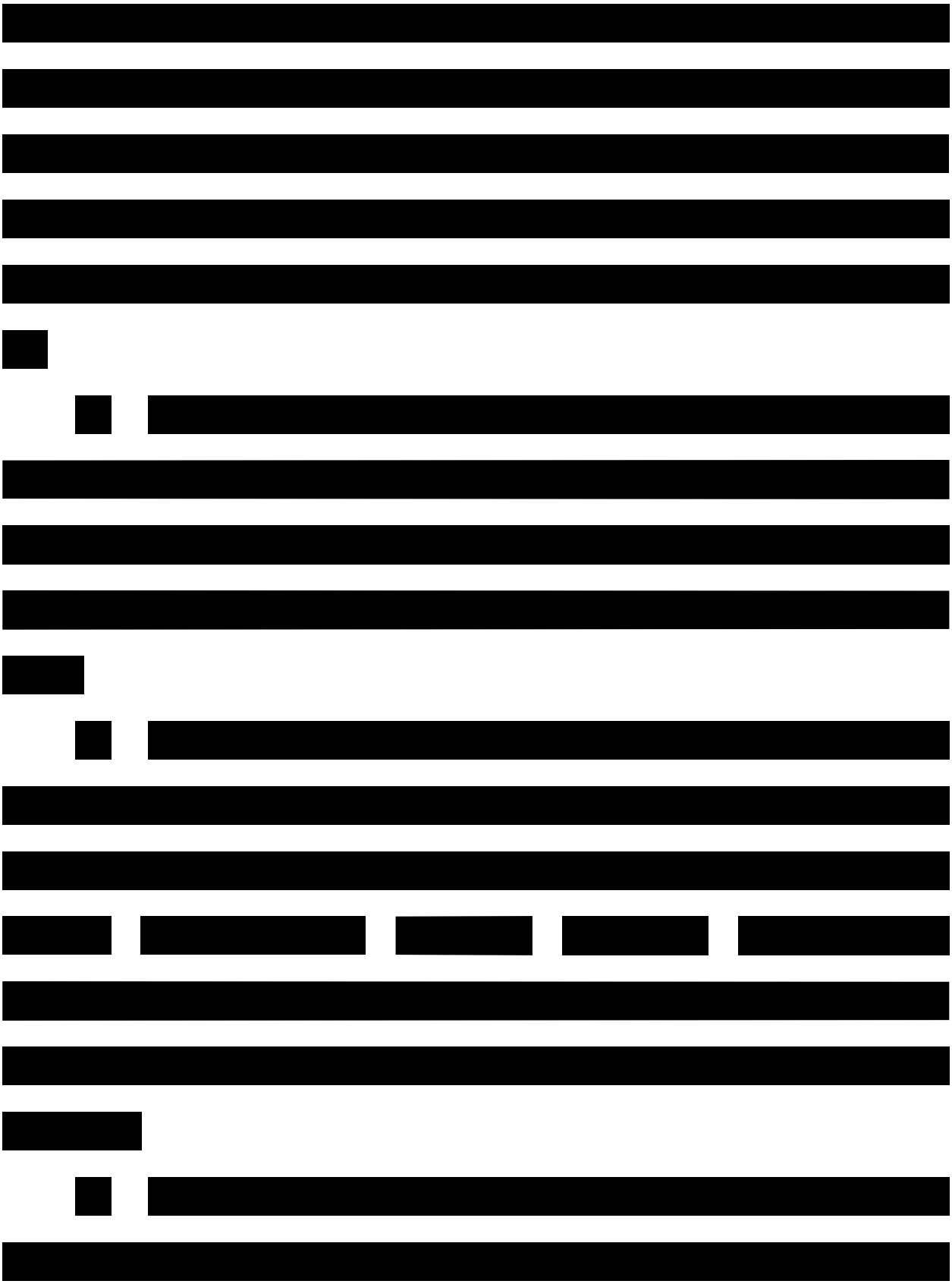

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108. ZHP has stipulated to the material gaps in its risk assessment of the zinc chloride process:

> Pursuant to Special Master Report and Order No. 56, in exchange for Plaintiffs' agreement not to further examine a witness at deposition regarding the statements identified herein, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") hereby stipulates as follows:
>
> 1. ZHP states that there are no health benefits associated with the presence of NDMA or NDEA in valsartan.
>
> 2. ZHP states that the publication *Purification of Laboratory Chemicals* (4th ed.) by W.L.F. Armarego and D.D. Perrin, which was first published in 1996 and documented scientific knowledge at that time, states on page 192 that DMF "[d]ecomposes slightly at its normal boiling point to give small amounts of dimethylamine and carbon monoxide."
>
> 3. ZHP states that it was required to perform a risk assessment in connection with the process change to the zinc chloride process. ZHP further states the following:
>
> a. ZHP states that the scientific research relied on to use DMF as part of the zinc chloride process did not include scientific research into the potential decomposition products of DMF under the conditions of the zinc chloride process.
>
> b. The risk assessment of DMF did not specifically evaluate whether DMF was degrading to yield dimethylamine as part of the zinc chloride process.
>
> c. Therefore, there is no document from Shanghai SynCores or ZHP that documents that potential degradation of DMF as part of the zinc

chloride process was evaluated as part of the risk assessment for the zinc chloride process.

d. ZHP states that it did not perform a risk assessment on the potential degradation of DMF because it did not realize that DMF would degrade in the way it ultimately degraded in the zinc chloride manufacturing process of valsartan. ZHP is not saying that it was not possible to know that DMF could degrade.

e. ZHP never identified the nitrosamine impurities in connection with its 2011 Risk Assessment and therefore did not evaluate the nitrosamine impurities as part of any steps of the risk assessment process.

4. With regard to the Change Request Form identified as Exhibit 195 to the March 28/29, 2021 deposition of Peng Dong (copy of Exhibit attached hereto as Exhibit 1), ZHP states the following:

a. The "Explanation Section" in Section 2 of the Change Request form on the page bearing Bates number ZHP01843067 provides a summary of the explanation for why the process change from the triethylamine hydrochloride process to the zinc chloride process was undertaken.

b. One of the reasons for the quality review described in Section 3 of the Change Request Form on the page bearing Bates number ZHP01843069 was to identify impurities due to the new process.

c. Section 3 of the Change Request Form on the page bearing Bates number ZHP01843070 provided that if this change was against CGMP code, it was supposed to be rejected.

(Ex. 91).

ZHP cGMP Expert David Chesney

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

118. Mr. Chesney was questioned about an article he authored titled, "Executive Responsibility for Quality," in the book titled, "Quality Management Essentials, Expert Advice on Building a Compliant System." (David Chesney Dep. Tr., 233:22-234:10), which stated in part:

> Executive commitment to quality in the pharmaceutical industry is critical, not only to ensure continuing profitability of the company, but also for the safety and well-being of patients and to meet the needs of healthcare providers who prescribe and use pharmaceutical products every day.
>
> * * *
>
> For these reasons, quality assurance (QA) and GMP compliance may be viewed differently in the pharmaceutical industry than in those industries where a reputation for high quality drives sales. Quality assurance may be viewed as a 'cost of doing business' or an internal 'police department' issuing directives that delay or prevent product release. That viewpoint can result in a low priority being assigned to quality operations and resourcing, which can lead in turn to quality problems, regulatory difficulties, unnecessary expense, adverse publicity, lawsuits and investor disappointment. **All these consequences are preventable if executive managers understand the importance of the quality assurance function and treat it as a critical business operation just like other critical areas, such as strategic planning, financial management and others**.
>
> * * *

> In addition to the business benefits, health regulatory agencies around the world both require and expect top management to support a strong quality assurance function for their companies.

(David Chesney Dep. Tr., 234:24-235:9, 236:23-238:11).

[redacted]

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The Discovery of the NDMA Contamination

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Representations and Warranties
Regarding Valsartan in the DMFs and ANDAs

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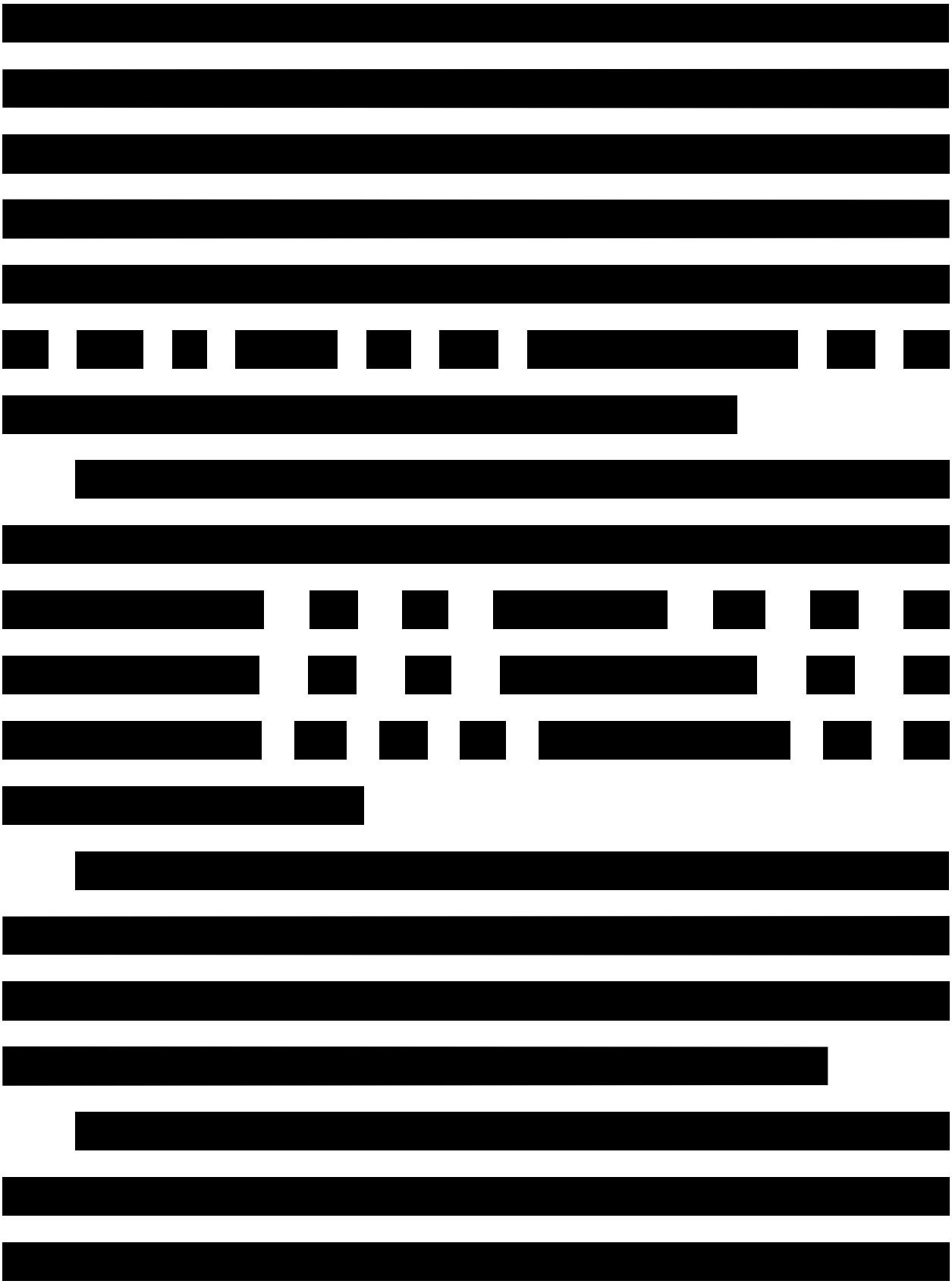

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ZHP's Valsartan Contained Probable Human Carcinogens and Presented an Unacceptable Carcinogenic Risk

[redacted]

[redacted]

[redacted]

[redacted]

Warranties and Representations

[redacted]

[redacted]

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The Warranties Were Breached

[redacted]

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Teva and Torrent Purchased and Utilized ZHP's Contaminated Valsartan

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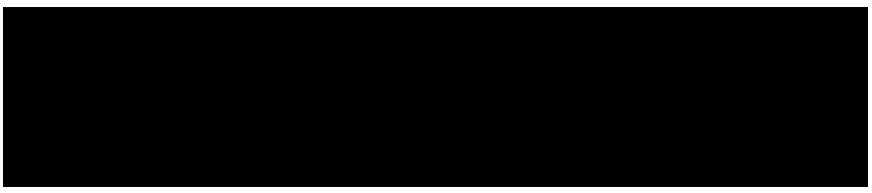

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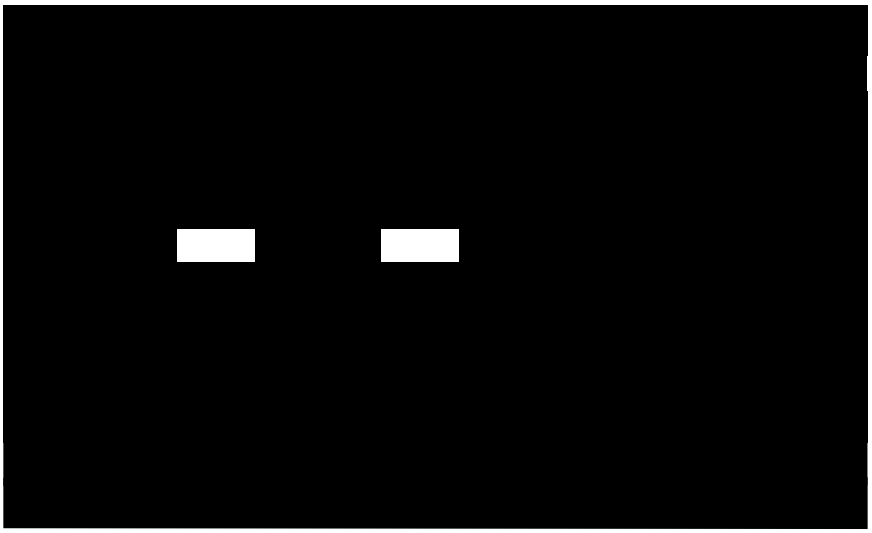

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The NDMA/NDEA Contamination of ZHP's API Could Have Been Easily Prevented

[redacted]

[redacted]

Dated: December 22, 2023

Respectfully submitted,

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